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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,104	10/09/2003	Dorotea Raventos Segura	10298.200-US	9207

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EXAMINER	
BAUGHMAN, MOLLY E	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,104	SEGURA ET AL.	
	Examiner	Art Unit	
	Molly E. Baughman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/9/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

   a. Claim 1, parts (b),(c),(d),(e),and (f), and claim 2 recite the limitation "the host cells." There is insufficient antecedent basis for this limitation in the claim. Part (a) of claim 1 only refers to "a host cell."

   b. Claim 1, part (e), recites the limitation "indicator cells." There is insufficient antecedent basis for this limitation in the claim. Part (d) of claim 1 only refers to the presence of "an indicator cell."

   c. Claim 3, part (a), recites the limitation "the host cells comprising the library polynucleotide sequence" in lines 27-28. There is insufficient antecedent basis for this limitation in the claim. Line 21 refers to a library of polynucleotide sequences, and line 24 refers to "a host."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 5, 7-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bylina et al (US 2002/0025537).

Bylina et al. discuss a method of screening for an antimicrobial peptide by screening a library consisting of a collection or population of members (i.e. DNA molecules) (page 3) (claims 3 and 10). A DNA library can be screened by cloning the DNA fragments into an expression vector, transforming a suitable host cell, inducing expression of the gene product encoded by the DNA fragment, and initiating a reaction which indicates the presence of the desired activity (page 4) (claims 1, 3 and 5). In one embodiment, *E.coli* cells are used for an inducible expression system that expresses active antimicrobial peptides (page 5) (claims 1,3, and 16-18). It is also noted that transformation can occur with various types of cells (bacterial, yeast, algal, plant or animal cell (page 4). Cells used are intended encompass archaea, bacteria, and eucarya (page 5) (claims 14-20). These cells can also be used to express the peptide library only for the purpose of producing the peptides (i.e. host cell). Cells can be deposited onto a filter and then onto a nutrient medium for the colonies to grow (claim 1, part (b), claim 2 part (a)). They are then transferred to another medium containing the inducer to initiate expression of a cloned gene (claim 1 part (c), claim 2 part (a)). If necessary, the colonies can be lysed by exposing them to chloroform vapor (page 6) (claims 12-13). The target cells, which indicate the effect of the peptides on cell viability, are grown on a second membrane filter and are placed in contact with the large library of peptide-expressing microcolonies to indicate which cells are producing an active peptide (page 9 and 11) (claims 1, 3, 5, 8, 10, and 12). Positive clones are characterized by DNA sequencing (page 10 and 11) (claim 9). Bylina et al. antimicrobial peptides of the invention to be "divided into four major structural classes: (1) beta-sheet structures with multiple disulfide bonds, such as the defensins; (2) alphahelical structures, such as the cecropins and magainins; (3) extended coils with a predominance of one or more amino acids, such as indolicidin, and (4) loop structures with a single disulfide bond, such as lactoferricin" (page 3).

3. Claims 1-10, 12, and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Stiles et al. (US 6,403,082).

Stiles et al. describe several methods for analyzing bacteriocins produced by various strains of gram negative and gram positive bacteria, and the secreted effect on various indicator strains (see Tables 1-5). Several plasmids were constructed with a promoter to induce genes encoding for several bacteriocins (divergicin A, specfically) and various leader peptides (colicin V, lactococccin A, and leucocin A) which enable the antimicrobial peptide to exit the host cell (example 3, columns 17-19). These plasmids were transformed into various host cells (*E.coli, Leuconostoc gelidum, Lactococcus lactis*), and grown in the presence of IPTG as an inducer (columns 18-21). Anatagonistic activity was observed with various plasmid constructed cells when they were overlayed onto a plate containing an indicator strain (*C.divergens* and *E.coli* DH5 specifically) (i.e. column 18, lines 42-45 and column 21, lines 3-7). Similar methods can also be applied to several indicator strains, sensitive to different plasmid constructs containing different bacteriocins (column 16, lines 41-46 and Table 5). The positive transformants were isolated, purified and sequenced (column 16, lines 47-67).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stiles et al. (US 6,403,082), as applied to claims 1-10, 12, and 16-19 above, in view of Shafikhani et al. (1997).

The teachings of the primary reference are stated above, including the instant claims 1-10, 12, and 16-19. While Stiles et al. describe using various gram-positive bacteria as hosts, they do not specifically discuss the use of *Bacillus subtilis*.

Shafikhani et al. discuss the use of *Bacillus subtilis* as a host in generating large libraries of mutants of the protease gene, which is actively secreted from the cell (page 305).

One of ordinary skill in the art would have been motivated to modify the method of Stiles et al. to use *Bacillus subtilis* as a host cell because the benefits of using *Bacillus subtilis* as a host cell for the generation of a library of peptides were shown by Shafikhani et al. The skilled artisan would have had a reasonable expectation of success in using *Bacillus subtilis* as a host cell in the method of Stiles et al. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods and use the claimed *Bacillus subtilis* therein.

SUMMARY

7. No claims are free of the prior art.

CONCLUSIONS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman
Examiner
Art Unit 1637
MEB 10/2/06

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
10/2/06